


PATENT COOPERATION TREATY
PCT
INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY
(Chapter II of the Patent Cooperation Treaty)
(PCT Article 36 and Rule 70)

Applicant's or agent's file reference JP802777/142	FOR FURTHER ACTION	See Form PCT/IPEA/416
International application No. PCT/NZ2004/000323	International filing date (<i>day/month/year</i>) 16 December 2004	Priority date (<i>day/month/year</i>) 19 December 2003
International Patent Classification (IPC) or national classification and IPC Int. Cl. <i>A61L 15/32</i> (2006.01), <i>A61K 38/00</i> (2006.01), <i>A61L 26/00</i> (2006.01) <i>A61K 9/70</i> (2006.01) <i>A61K 38/17</i> (2006.01) <i>A61P 17/02</i> (2006.01)		
Applicant KERATEC LIMITED et al		

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36. 2. This REPORT consists of a total of 3 sheets, including this cover sheet. 3. This report is also accompanied by ANNEXES, comprising: a. <input type="checkbox"/> (<i>sent to the applicant and to the International Bureau</i>) a total of sheets, as follows: <div style="margin-left: 20px;"> <input type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions). <input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box. b. <input type="checkbox"/> (<i>sent to the International Bureau only</i>) a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or table related thereto, in electronic form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions). </div>	4. This report contains indications relating to the following items: <div style="margin-left: 20px;"> <input checked="" type="checkbox"/> Box No. I Basis of the report <input type="checkbox"/> Box No. II Priority <input type="checkbox"/> Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability <input type="checkbox"/> Box No. IV Lack of unity of invention <input checked="" type="checkbox"/> Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement <input type="checkbox"/> Box No. VI Certain documents cited <input type="checkbox"/> Box No. VII Certain defects in the international application <input type="checkbox"/> Box No. VIII Certain observations on the international application </div>
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Date of submission of the demand 11 July 2005	Date of completion of this report 06 April 2006
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INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/NZ2004/000323

Box No. I Basis of the report

1. With regard to the language, this report is based on:

☒ The international application in the language in which it was filed

☐ A translation of the international application into translation furnished for the purposes of:

, which is the language of a

☐ international search (under Rules 12.3(a) and 23.1 (b))

☐ publication of the international application (under Rule 12.4(a))

☐ international preliminary examination (Rules 55.2(a) and/or 55.3(a))

2. With regard to the elements of the international application, this report is based on (*replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report*):

☐ the international application as originally filed/furnished

☒ the description:

pages 1, 2, 5-20 and 24 as originally filed/furnished

Pages 3 and 4 received by this Authority on 18 October 2005 with the letter of 18 October 2005

pages* received by this Authority on with the letter of

☒ the claims:

pages 22 and 23 as originally filed/furnished

pages* as amended (together with any statement) under Article 19

pages* 21 received by this Authority on 18 October 2005 with the letter of 18 October 2005

pages* received by this Authority on with the letter of

☒ the drawings:

pages 1/3-3/3 as originally filed/furnished

pages* received by this Authority on with the letter of

pages* received by this Authority on with the letter of

☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing.

3. ☐ The amendments have resulted in the cancellation of:

☐ the description, pages

☐ the claims, Nos.

☐ the drawings, sheets/figs

☐ the sequence listing (*specify*):

☐ any table(s) related to the sequence listing (*specify*):

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

☐ the description, pages

☐ the claims, Nos.

☐ the drawings, sheets/figs

☐ the sequence listing (*specify*):

☐ any table(s) related to the sequence listing (*specify*):

* If item 4 applies, some or all of those sheets may be marked "superseded."

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims 15, 18, 19, 21 and 22	YES
	Claims 1-14, 16, 17 and 20	NO
Inventive step (IS)	Claims	YES
	Claims 1-22	NO
Industrial applicability (IA)	Claims 1-22	YES
	Claims	NO

2. Citations and explanations (Rule 70.7)

CITATIONS:

D1: WO 2003/011894

D2: US 5,932,552

D3: WO 2003/103737

D4: AU 2002330798

EXPLANATION:

D1 discloses the production soluble keratin derivatives. The keratin protein fraction that is produced is intact and are S-sulfonated keratin intermediate filament proteins and S-sulfonated keratin high sulphur proteins.

D2 discloses keratin hydrogel which can be used as a wound dressing. The disulfide linkages in keratin are reformed.

D3 discloses keratin material that is S-sulfonated and enriched in intermediate filament proteins. **D3** further discloses S-sulfonated keratin intermediate filament protein powder. The keratin material disclosed in **D3** is used in the treatment of bone fractures.

D4 discloses the production of keratin derivatives of the present invention in the form of films, fibers, foams and adhesives and an extension of the use of these in medical materials.

NOVELTY (N) Claims: 1-14, 16, 17 and 20

Claims 1-8 are not novel in light of the disclosure of **D1**, **D3** or **D4** because the phrase 'a material for treating a wound' renders keratin protein fraction to be only suitable for treating wounds. Therefore keratin protein fractions of **D1**, **D3** or **D4** that are suitable for such use deprive claims 1-8 of their novelty. Claim 9 is not novel in light of the disclosure of **D4** which discloses a fiber, film or a foam of the present keratin protein fraction. Claims 1, 10-14, 16, 17 and 20 are not novel in light of the disclosure of **D2** which discloses intact keratin protein fraction containing wound hydrogel. **D2** further discloses that formulation of hydrogel involves treating keratin with reductant ammonium thioglycollate. Therefore claims 1, 10-14, 16, 17 and 20 lack novelty.

INVENTIVE STEP Claims 1-22

Claims 1-14, 16, 17 and 20 as for novelty. Claims 1-22 lack inventive step in light of the disclosure of **D1**, **D3** or **D4** when combined with the disclosure of **D2**. The skilled person would formulate the wound dressing or hydrogel of **D2** by substituting the keratin of **D2** with keratin protein fraction of **D1**, **D3** or **D4**. Therefore claims 1-22 lack an inventive step.